K100833

**SECTION E**
**510(k) SUMMARY**

JUN - 3 2010

**1. SUBMITTER INFORMATION:**


Name: OSspray Ltd.
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Royston
Herts
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United Kingdom

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Contact: Ian Thompson, Ph.D.

Preparation Date: March 2010

**2. DEVICE NOMENCLATURE:**
Trade Name: Sylc™ SmarTip™
Common Name: n/a
Regulation Code: 872.4200
Classification Name: EJR

**3. LEGALLY MARKETED PREDICATE DEVICES:**
3.1 Physical characteristics and method of application:

Device Name: AirFlow Handy
510(k) Number: K991875
Applicant: EMS, SA.

3.2 Physical Characteristics, Method of manufacture and method of application:

Device Name: Groman PrepMaster
510(k) Number: K030292
Applicant: Groman Dental.

3.3 Physical and Chemical Characteristics and Mode of Action;

Device Name: OSspray Cleaning Compound, also Trade named - Sylc™
510(k) Number: K062502
Applicant: OSspray LTD.

**4. DEVICE DESCRIPTION:**
Sylc™ SmarTip™ is a single-use, disposable hand-held device that utilizes a standard dental hand piece air source, and is designed to project a stream of dry particulate onto a tooth surface to clean tooth surfaces and close exposed dentin tubules. The process of cleaning the tooth surface physically occludes dentin tubules for the management of sensitive teeth.

The powder chamber contains OSspray Cleaning Compound (K062502) which is a dry inorganic particulate, (calcium sodium phosphosilicate). When exposed to an aqueous environment, the material undergoes a rapid surface reaction, allowing it to physically adhere to exposed dentin and to physically occlude tubules. Within a short period of time, essentially all of the particles react to form hydroxycarbonate apatite (HCA), which is chemically and structurally similar to natural tooth mineral.

**5. INTENDED USE:**

Sylc™ SmarTip™ is a disposable, single-use product intended for the prophylaxis and polishing of enamel surfaces and to provide rapid relief of hypersensitivity associated with exposed tooth dentin. Studies have shown that OSspray Cleaning Compound contained in the device is effective at occluding exposed dentinal tubules, which has been shown in the literature to be associated with a reduction in hypersensitivity.

**6. TECHNOLOGICAL CHARACTERISTICS:**

The technological characteristics of Sylc™ SmarTip™ and AirFlow Handy are similar, but not identical. Both devices function by mixing the polishing powder with compressed air, accelerating the particles through a tube to impact against the target tooth surface. Both devices use standard compressed air available at the dental operatory chair.

The primary difference between the two devices is that Sylc™ SmarTip™ is a single use, disposable device that comes with a reusable adapter that delivers OSspray Cleaning Compound (K062502). The SmartTip™ is discarded after each use whereas the AirFlow Handy is a reusable device that must be dis-assembled and sterilized after every use. AirFlow Handy has a built in powder chamber which can be filled with any number of dry powders for the intended application.

Sylc™ SmarTip™ and Groman PrepMaster are both disposable single use devices that comes pre filled with a dry powder. Sylc™ SmarTip™ and Groman PrepMaster are manufactured using the same materials and operate using the same principles. Both devices use standard compressed air at the operatory. Both use standard adapters to connect to the operatory air supply to mix the dry powder with air in the chamber and expel it onto the tooth surface. Sylc™ SmarTip™ differs from PrepMaster in that Sylc™ SmarTip™ is filled with OSspray Cleaning Compound identical to that cleared in 510(k) K062502, and is used in a standard prophylaxis and polishing procedures whereas the PrepMaster utilizes other dry powder compounds.

**7. SAFETY AND PERFORMANCE DATA:**

The Performance Testing was conducted with Sylc™ SmarTip™ on a statistically relevant number of samples to demonstrate the effectiveness of cleaning and of tubule occlusion on dentin slabs in-vitro. The results indicate that Sylc™ SmarTip™ is effective delivering appropriate amounts of OSspray Cleaning Compound to the tooth surface and that it is effective at cleaning extrinsic stains on teeth and that it occludes a statistically significant number of tubules when compared with negative controls.

Performance testing was also conducted to insure that the connection of the SmarTip to the adapter and air hose remained intact when subjected to air pressure of 45psi. In addition, this testing demonstrated that at 45psi max pressure there were no leaks in the units and that powder was expelled properly.

The biocompatibility of the OSspray Cleaning Compound contained within the device has previously been evaluated for cytotoxicity (L-929), intracutaneous irritation, maximization sensitization. The results of these tests indicate that there is no evidence of any hazardous effects to the patient if the product is

used as directed. (See 510(k) K062502). The materials used in the manufacture of the Sylc™ SmarTip™ device are medical grade polypropylene and surgical grade 316L stainless steel.

**8. CONCLUSIONS:**

Sylc™ SmarTip™ is considered to be substantially equivalent to the legally marketed predicate device, AirFlow Handy (K99187) and Groman PrepMaster (K030292). Furthermore, the material delivered to the patient is the OSspray Cleaning Compound (K062502). The provided *in vitro* performance and biocompatibility data demonstrate the safety and efficacy of Sylc™ SmarTip™ for the intended uses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OSspray, Limited
C/O Mr. David C. Greenspan
President
Spinode Consulting
3116 N.W. 62nd Terrace
Gainesville, Florida 32606

JUN - 3 2010

Re: K100833
Trade/Device Name: Sylc™ SmarTip™
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Codes: EFB and EJR
Dated: March 17, 2010
Received: March 24, 2010

Dear Mr. Greenspan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.\

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## SECTION D
## STATEMENT OF INDICATIONS FOR USE

**510(k) Number (if known):** K100833

**Device Name:** Sylc™ SmarTip™

**INDICATIONS FOR USE:**
Sylc™ SmarTip™ is a disposable, single-use device containing OSspray Cleaning Compound powder, intended for prophylaxis and polishing of dental enamel surfaces and rapid relief of hypersensitivity associated with exposed tooth dentin. Studies have shown that Sylc™ SmarTip™ is effective at occluding exposed dentinal tubules, which has been shown in the literature to be associated with a reduction in hypersensitivity.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use __X_ OR (Per 21 CFR 801.109) Over-The-Counter Use ____

Robert MS for Dr. K.L. Mulay

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K100833